SUBJECT INFORMATION AND INFORMED CONSENT FORM
AND
AUTHORIZATION TO DISCLOSE HEALTH INFORMATION

Sponsor / Study Title:	**Midland Research Group Inc. / "Efficacy, Safety, and Tolerability of Switching EFV/TDF/FTC to BIC/FTC/TAF in Virologically Suppressed Adults with HIV-1 Infection."**
Protocol Number:	**IN-US-380-4543**
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INTRODUCTION TO A CLINICAL RESEARCH STUDY

You have been asked to take part in a clinical research study. First, we want you to know that you can choose not to take part in it. Second you need to know that there are some big differences between being in a study and the regular care you get from your doctor:

- Outside of a research study, you and your doctor have a great deal of freedom in making decisions about your healthcare.
- When you take part in a research study, the main goal is to learn things to help other people in the future. The study team (your study doctor and the research staff that assist your study doctor) will follow the requirements for the research study.

It's important that you understand the difference between the regular care you get from your doctor and what's involved in this research study.

This Subject Information and Informed Consent (ICF) describes the purpose, procedures, benefits, risks, discomforts, and precautions of the study. It also describes alternative

procedures that are available to you and your right to withdraw from the study at any time. Your study doctor or study coordinator will go over this ICF with you and answer any questions you may have regarding the study. Ask your study doctor or study coordinator to explain any words or information in this ICF you do not clearly understand. No guarantees or assurances can be made as the results of the study.

Please read this information carefully before deciding to take part. Research studies are voluntary and include only those who wish to take part. No one can force you to take part in this study and you can stop at any time. If you choose to take part in this research study, you will be asked to read, date and sign this ICF and you will receive a copy of the signed and dated document for your records.

This research study is being conducted by Midland Research Group Inc. They are sponsoring the study and will be paying the study doctors listed above to conduct the study. As a sponsor of the study, Midland Research Group Inc. is receiving funds and study drug from Gilead Sciences, Inc.

Before you decide to take part, please take as much time as you need to ask questions with your study team, with family and friends, or with your personal doctor or other healthcare professional. Feel free to take the time to make an informed decision for yourself and your healthcare.

This study has been approved by Chesapeake IRB. Chesapeake is an independent committee established to help protect the rights of research subjects. This does not mean the IRB has approved your participation in the study. You must think about the information in this ICF document for yourself. You must then decide if you want to be in the study.

BACKGROUND AND PURPOSE

You are being asked to participate in this research study because you have HIV (also known as the virus that causes AIDS). You are currently taking a single-tablet HIV medication known as ATRIPLA®. ATRIPLA® contains the components Efavirenz Tenofovir Disoproxil Fumarate), and Emtricitabine.

The component Tenofovir Disoproxil Fumarate (TDF) in ATRIPLA® may cause kidney damage and decreased bone density over time. In addition, the component Efavirenz (EFV) in ATRIPLA® may cause sleep disturbances, depression, and anxiety overtime.

The purpose of this research study is to evaluate the safety and effects of switching from the single tablet regimen ATRIPLA® to a single tablet regimen containing Bictegravir, Tenofovir alafenamide fumarate (TAF), and Emtricitabine (FTC), BIKTARVY® (also referenced as “study drug” throughout this consent).

The integrase strand transfer inhibitors are guideline recommended as components of First-line antiretroviral therapy in combination with 2 nucleoside reverse transcriptase inhibitors (NRTIs). HIV uses integrase (an HIV enzyme-an enzyme is a protein that starts or increases the speed of a chemical reaction) to insert its viral DNA into the DNA of the host CD4 cell. Blocking integrase prevents HIV from replicating.

Bictegravir (BIC, B) is a powerful new HIV integrase strand transfer inhibitor (INSTI) with a high barrier to resistance, low potential for drug-drug interactions and the longest half-life compared with marketed INSTIs.

BIC is co-formulated with the approved nucleoside analog reverse transcriptase backbone of Emtricitabine (FTC)/Tenofovir alafenamide (TAF) into a single tablet regimen, dosed once daily without regard to food. Emtricitabine /Tenofovir alafenamide is commercially available as Descovy®.

Both Emtricitabine (FTC, F) and Tenofovir alafenamide (TAF) belongs to a class (group) of HIV drugs called nucleoside analog reverse transcriptase inhibitors (NRTIs). NRTIs block another HIV enzyme called reverse transcriptase. By blocking this enzyme, they prevent HIV from replicating. They are used in combination with other antiretroviral agents—sometimes called cocktails--for the treatment of HIV-1 infection in adults and children.

In over 3 years FTC/TAF-based regimens have demonstrated improved bone and renal safety when compared with FTC/TDF- based regimens (like ATRIPLA®) with no discontinuation due to renal tubulopathy including Fanconi syndrome.

B/FTC/TAF, BIKTARVY® has been approved by the Food and Drug Administration (FDA) for the treatment of HIV-1 infection.

- In a treatment naïve phase 2 study with 65 subjects 97% remained virologically suppressed through 48 weeks, all with no emergence of resistance and the drug was well tolerated.
- In 2 treatment naïve Phase 3 studies with over 1200 subjects, B/F/TAF was safe and efficacious through 48 weeks compared with dolutegravir (DTG)-containing regimens – no subject developed resistance to study drugs.
- In a treatment experience Phase 3 study with over 520 subjects B/F/TAF was safe and efficacious (the drug worked) through 48 weeks in subjects switching from boosted protease inhibitors and 2 NRTIs. No subject developed resistance on B/F/TAF.
- The efficacy and safety of B/F/TAF in virologically suppressed subjects are being evaluated in 4 other Phase 3 studies with over 1500 subjects switching from on DTG –based regimen; INSTIs-based regimen and other third agents

NUMBER OF SUBJECTS / LENGTH OF PARTICIPATION

The goal of the study is to obtain 100 subjects to participate in this study at your study

doctor's site. Your participation in this study will last at least 48 weeks. The study includes approximately 8 visits to the study site.

STUDY PROCEDURES

Before any study-related tests and procedures are performed, you will be asked to read, date and sign this ICF document.

After study eligibility has been determined during the Screening visits (visits where your study doctor will determine if you qualify for participation in the study) you may participate in approximately six more clinic visits at designated time intervals. You will be asked to remain at the clinic during each study visit. The first visit will determine if you may qualify to participate in the study. Additional visit(s) may be needed to be sure if you can (qualify to) participate in the study.

The following tests and procedures will be performed to determine if you qualify to take part in this study:

Screening Visit 1:

- You will be asked to sign and date this informed consent form (ICF) before any study procedures are performed.
- Study site personnel will review your medical history, inclusion/exclusion criteria (the criteria that will allow you to be included in the study (inclusion), the criteria that would keep you from being in the study (exclusion) and to see whether or not, you are able to participate in the study).
- You will be asked for information including: your age, race, smoking history and habits, medical/surgical history (including cardiovascular (heart) risk factors and history), age of onset of HIV (when you were first diagnosed), historical genotype(s), and all the medicines you are currently taking (including your current HIV medication).
- Your study doctor will review your current medications.
- If you are using medications not allowed in the study, you will be asked to stop taking this medication and the study doctor will have them changed to a different medication that may work for you.
- You will have a complete physical examination including vital signs (temperature, heart rate, and blood pressure), height and weight to help make sure you do not have some medical problems that would prevent you from safely participating in the study.
- If you are a woman who can have a child, you will have a urine test to see if you are pregnant unless it is documented in your medical history (you may be asked to sign a separate authorization for release of your medical records) that you have had a

procedure that prevents you from becoming pregnant (hysterectomy, oophorectomy, or bilateral tubal ligation) or you are at least 2 years post-menopausal.
- You will have blood and urine samples collected for testing in a laboratory.
- Your next clinic visit will be scheduled, and you will be asked to continue your current HIV medication.

Baseline Visit or Day 1

You will return to the study site within 30 days of the first visit for the, Baseline/Day 1 visit. Study site personnel will review inclusion/exclusion criteria of the study and confirm, whether or not, you are able to continue in the study, prior to this visit. Please do not take your HIV medication the day of the visit, because you will be assigned study drug on that day. During this visit you will be asked to have the following test and procedures:

- You will read the Pittsburgh Sleep Index and HIV Symptom Index Questionnaires, otherwise referred to as, Patient Reported Outcome (PRO) questionnaires and write/mark answers directly onto the questionnaire. (This will take no more than five minutes)
- You will be asked about any medical issues you may have had since your last visit.
- You will be asked about any medications changes.
- You will have a physical examination including vital signs (temperature, heart rate, and blood pressure), height and weight.
- You will have fasting blood and urine samples collected for testing.
- If you are a woman able to bear children, you will have a urine pregnancy test
- You will be given study drug and take your first dose on site.
- The study team will take to you about the importance of adherence and taking the study drug at the same time each day.
- You will be asked to bring the all study drug to the next visit.

Study Visits 4, 8, 12, 24, and 36 (Weeks 4-36)

- You will read the Patient Reported Outcome (PRO) questionnaire and write/mark answers directly onto the questionnaire. (This will take no more than five minutes)
- You will be asked about any medical issues you may have had since your last visit.
- You will be asked about any medications changes.
- You will have a physical examination including vital signs (temperature, heart rate, and blood pressure), height and weight.
- You will have blood (fasting for Weeks 12, 24, and 36) and urine samples collected for testing laboratory values.
- If you are a woman able to bear children, you will have a urine pregnancy test
- You will return study drug and provide it to the study team for reviewing how well you are taking it.
- You will be given study drug.

- The study team will talk to you about the importance of adherence and taking the study drug at the same time each day.
- You will be asked to bring the all remaining study drug to the next visit

Final Visit 48

You will return to the study clinic for a final visit. The following procedures will be done:

- You will read the Patient Reported Outcome (PRO) questionnaire and write/mark answers directly onto the questionnaire. (This will take no more than five minutes)
- You will be asked about any medical issues you may have had since your last visit.
- You will be asked about any medications changes.
- You will have a physical examination including vital signs (temperature, heart rate, and blood pressure), height and weight.
- You will have fasting blood and urine samples collected for testing laboratory values.
- If you are a woman able to bear children, you will have a urine pregnancy test (a urine sample will be collected for this test).
- You will return study drug and provide it to the study team for reviewing whether you are taking your study drug as instructed.
- You will be provided with a script to take to your pharmacy to ensure continued treatment of HIV.
- The study team will talk to you about the importance of adherence and taking your HIV medications at the same time each day.

SCHEDULE OF STUDY EVENTS

	Screening Visit	Day 1 [a]	Week 4 [a]	Week 8 [a]	Week 12 [b]	Week 24 [b]	Week 36 [b]	week 48 [c]	Early Discontinuation
Informed Consent	X								
Patient Questionnaires		X	X		X			X	X
Height	X								
Weight	X	X	X	X	X	X	X	X	X
Vital Signs	X	X	X	X	X	X	X	X	X
Complete Medical History & Physical Exam	X								
Concomitant Medication Review	X	X	X	X	X	X	X	X	X
Assess for Adverse Experiences			X	X	X	X	X	X	X
Abbreviated History & Physical Exam		X	X	X	X	X	X		
Hematology	X	X	X	X	X	X	X	X	X

	SCREENING VISIT	DAY 1 [a]	WEEK 4 [a]	WEEK 8 [a]	WEEK 12 [b]	WEEK 24 [b]	WEEK 36 [b]	WEEK 48 [c]	EARLY DISCONTINUATION
Chemistry	X	X	X	X	X	X	X	X	X
CD4 Profile	X	X	X	X	X	X	X	X	X
HIV- RNA Quantitative	X	X	X	X	X	X	X	X	X
Fasting Lipid Profile		X			X	X	X	X	X
Plasma and serum Storage Sample		X	X	X	X	X	X	X	X
Urinalysis	X		X	X	X	X	X	X	X
Hepatitis B Surface antigen, Surface antibody, and Core Antibody [d]	X								X
Hepatitis C antibody [e]	X								X
Plasma Hepatitis B viral load [f]	X		X	X	X	X	X	X	X
Females of childbearing potential: Pregnancy Test (Urine)	X	X	X	X	X	X	X	X	X
Dispensing / Administration of Study Drug		X	X	X	X	X	X		
Counting of Returned Study Drug			X	X	X	X	X	X	X

[a] ±2 days, [b] ±6 days, [c] ±6 days, [d] If Hepatitis B Surface antigen positive or if Ag/Ab negative with Core antibody positive: plasma qualitative and quantitative HBV DNA, Hepatitis B virus e-antigen and antibody, [e] If Hepatitis C antibody positive, HCV RNA will be performed, [f] If Hepatitis B coinfected

Blood Sampling

Blood samples, about 5 ml or one teaspoon each, will be taken approximately 8 times throughout the course of the study with approximately 25 mL of blood (about 5 teaspoons) being drawn in total. For comparison, a standard blood donation at a blood collection center, once in any 56-day period, is about 2 cups of blood.

Additional blood samples may be required if any of your lab values are abnormal. Additional blood samples may be drawn during the study if the study doctor considers it necessary for monitoring your health.

It is possible that more than one attempt to obtain a blood sample may be necessary. At each visit where blood is collected, a needle will be inserted into a vein in your arm in order to collect blood samples.

SUBJECT RESPONSIBILITIES

If you participate in this study, you will be expected to:

- Take study drug as instructed by study staff once a day, at the same times from day to day.
- Do not take any new medications unless your study doctor has agreed to it. If possible, speak with your study doctor before taking any new medications.
- You are not allowed to take any of these medications during the study:
    - Dofetilide, Phenobarbital, Phenytoin, Carbamazepine, Oxcarbazepine, Rifampin, Rifapentine, Rifabutin, Any other HIV medication other than the study drug, Cisapride, St. John's Wort, Echinacea.
- Do not consume illicit drugs or drugs of abuse during your participation in the study.
- If you are a woman of child bearing potential, you will be required to use effective birth control methods during the study (your study doctor/study site personnel will discuss birth control options).
- Tell your study staff all the information you know about your health and the medications you may be taking throughout the study period. If you do not tell the study staff everything you may be putting your health at risk.
- Tell your study staff as soon as you can if you are treated by another doctor (for example, in an emergency) and you should inform any treating doctors of your involvement in this study.
- Tell the study doctor/study staff about any changes in your health or problems that you are having (for example, going to the emergency room).
- Tell the study staff about any medications or remedies, including natural or herbal products, which you are taking even if they are obtained without a prescription.
- Do not participate in any other investigational studies (studies of drugs that are not yet approved by the US FDA or other Regulatory Authorities of other countries).
- Follow all procedures given to you while you are participating in the study. If you do not, you may be discontinued from the trial. If you are unsure about what you are supposed to do, ask the study staff.
- Bring your unused study drugs and all empty study drug containers to each of your study visits.
- If you decide to drop out or are not allowed to continue in the study, you may be asked to come in as soon as possible after taking your last dose of study drug. The study staff will ask about any medications you are taking and how you are feeling, obtain laboratory samples (blood), and collect all study drugs provided to you, ask you to complete the PRO questionnaire and return you to your previous HIV medication.
- Complete your subject PRO Questionnaire at every visit after screening.
- It is important that you keep unused study drug out of the reach of children and those who do not have the ability to understand and that the study drug is only taken by you.
- If you forget to follow these instructions in preparation for your study visit, contact the study staff personnel and let them know. Your visit may need to be rescheduled.

RISKS, POSSIBLE SIDE EFFECTS AND/OR DISCOMFORTS

You may experience some, none or, all of these side effects, and they may be mild, moderate, or severe, and potentially life-threatening. There is always the risk of a very rare or unknown side effect that may occur. If any of these side effects occur, you must tell the study site personnel as soon as possible. If you are not honest about your side effects, it may not be safe for you to stay in the study. If a severe reaction to the study drug occurs, the study doctor may stop the study drug. You will be monitored for all side effects. Many side effects go away shortly after you stop taking the study drug. However, sometimes side effects can be serious, long lasting or permanent. If you do not understand what any of these side effects mean, please ask the study doctor or study staff to explain these terms to you.

For BIC/FTC/TAF - BICTARVY®

The following side effects have been observed during treatment with BIC/FTC/TAF (BIKTARVY®):

Bictegravir/Emtricitabine/Tenofovir alafenamide (B/F/TAF)
B/F/TAF (50/200/25 mg), BIKTARVY® is a tablet containing three medications: bictegravir (BIC, B, GS- 9883), emtricitabine (FTC, F) and tenofovir alafenamide (TAF). The safety information known about this tablet is from study GS-US-141-1475, in which 65 subjects who had never been treated for HIV received BIC (75 mg) + F/TAF (200/25 mg) for 48 weeks.

A very common adverse event (more than or equal to 10%) included:

- Diarrhea

Common adverse events (seen in more than 5-10% of people) included:

- Headache
- Nausea
- Fatigue (feeling tired)
- Joint pain
- Back pain

Adverse drug reactions that have been identified in studies of more than 800 subjects treated for a year with F/TAF are as follows:

Very common (more than or equal to 10%):

- Headache
- Diarrhea
- Nausea
- Fatigue

Common (more than or equal to 1% and less than 10%):

- Vomiting
- Abdominal pain
- Indigestion
- Passing gas
- Rash

Following a chronic 39 week study in monkeys, animals administered the highest dose of bictegravir (1000 mg/kg/day) had bile duct hyperplasia (increased cell growth) and hypertrophy (increased cell size), and some increased cell growth and inflammation in nearby liver cells. These effects were not seen in monkeys administered the mid-level dose (200 mg/kg/day), and these animals had BIC levels in the blood that were approximately 5-times higher than the blood concentrations in humans when given the B/F/TAF tablet. No adverse drug reactions associated with liver or bile duct problems has been identified in humans treated with bictegravir. However, if you experience jaundice (skin or eyes turning yellow), abdominal pain, ongoing nausea, loss of appetite, or other possible liver or bile duct related problems, please report this to your study doctor immediately.

In a study in pregnant rats, a possible effect on the fertility of male and female baby rats born to mothers given BIC 300 mg/kg/day was observed. The decreases in fertility were slight and remained within the range seen in animals not given any drug in other studies. At the next-lowest dose, 10 mg/kg/day, no effects were noted in the baby rats. At this dose, the mother's BIC plasma exposure was approximately 8-times higher than the estimated blood concentrations of BIC in humans when administered as B/F/TAF (50/200/25 mg).

You may feel discomfort during some of the tests and may also have risks, such as:

- Blood samples: possible side effects from blood drawing include faintness, inflammation of the vein, pain, bruising, or bleeding at the site of puncture. There is also a slight possibility of infection.

Hepatitis Testing: Some of your blood will be tested for hepatitis B and hepatitis C. The study doctor may be required by law to report a positive test result to the local health authority.

UNFORESEEN RISKS

All medications have a potential risk of an allergic reaction, which if not treated promptly, could become life-threatening. You should get medical help and contact the study doctor right away if you think you have any of the following symptoms of a serious allergic reaction: trouble breathing, or swelling of the face, mouth, lips, gums, tongue or neck. Other allergic reactions may include rash, hives, or blisters. It is important that you immediately inform your study doctor about any changes in your health.

PREGNANCY/BIRTH CONTROL

It is not known whether the study drug(s) may affect an unborn baby and their effects **may be hazardous**. It is important that women must not become pregnant during this study. Effective birth control must be used by women who are still able to become pregnant from the screening visit until the end of the study (Screening Visit to Visit Week 48).

If you are female and wish to participate in this study, you must:

- be of non-child bearing potential [for example, physiologically incapable of becoming pregnant, including any female who is 2 years post-menopausal, or surgically sterile (defined as having a bi-lateral oophorectomy, hysterectomy or tubal ligation)]
- be of child bearing potential, have a negative serum pregnancy test (blood test) or urine at Screening Visit to Visit Week 48, and agree to one of the following acceptable birth control methods used consistently and correctly as stated below for the duration of the study – from Visit 1 (Screening) until 14 days after Visit Week 48:

    - Not have sex while in the study; or
    - Use hormonal contraceptive such as
        - Oral contraceptive
        - Contraceptive implant
        - Injectable hormonal contraceptive
    - Use a double barrier method such as
        - Condom plus intrauterine device (IUD)
        - Diaphragm plus spermicide
    - Maintain a sexual relationship with the same male partner (a monogamous relationship) throughout the study who has had a vasectomy (surgically sterilized)

If you think that you have become pregnant during the study, it is important that you inform the study staff immediately. If you become pregnant or think that you may be pregnant, you will be removed from the study and the study staff will refer you to seek the appropriate care, the cost of which will be your responsibility. The study staff may request to track your pregnancy and will report the pregnancy to the Sponsor and the IRB.

ALTERNATIVE TREATMENT

You do not have to be in this study to receive treatment for your HIV. Instead of taking part in this study, you may choose to simply continue treatment with your current HIV drug or ask your primary doctor about other options that are available for treatment.

The study doctor will discuss with you the risks and benefits of alternative treatments.

NEW CLINICAL DATA FINDINGS

Any new important information that is discovered during the study and which may influence your willingness to continue participation in the study will be made available to you.

POSSIBLE BENEFITS OF THE STUDY

You may or may not benefit as a result, of your participation in this study. However, there is no guarantee that you will benefit from your participation in this study. Results from this study may benefit others in the future.

COMPENSATION FOR PARTICIPATION

There is no compensation for participating in this study.

CONFIDENTIALITY

To ensure that your information collected for this study will be kept private, your name will not be used whenever possible. A code will be used instead of your name. All of your study data will be kept in a secure location.

Records of your participation in this study will be held confidential except as disclosure is required by law or as described in this informed consent document. The study staff, the sponsor or persons working on behalf of the sponsor and under certain circumstances, the US FDA and other health authority agencies and the IRB will be able to inspect and copy confidential study-related records which identify you by name. Therefore, absolute confidentiality cannot be guaranteed. If the results of this study are published or presented at meetings, you will not be identified.

You will provide informed consent and this consent will include allowing access to medical records and to contact doctors and family to record vital status even after the subject has discontinued participation in the study.

COMPENSATION FOR INJURY

If you are injured directly from the study drug, the sponsor, Midland Research Group Inc., will pay for the reasonable costs of medical treatment, to the extent they are not covered

by your medical or hospital insurance. Midland Research Group Inc. will not offer payment for expenses that are in any way attributable to the negligence, misconduct, error or omission of any person employed by, or acting on behalf of the study doctor/study site personnel or the study site or to your failure to follow instructions. Midland Research Group Inc. has no plans to provide any other form of compensation, such as lost wages or payments for emotional distress.

You must notify the study doctor immediately of any research-related injury and the nature of the expenses to be covered. If you have any questions concerning the availability of medical care or if you think you have experienced a research-related illness, injury or emergency, contact the study doctor listed on page one of this informed consent.

To pay these medical expenses, the sponsor will need to know some information about you like your name, date of birth, and social security number or Medicare Health Insurance Claim Number. This is because the sponsor has to check to see if you receive Medicare and if you do, report the payment it makes to Medicare.

You will not lose any of your legal rights or release the Sponsor, the study doctor, the study staff, or study site from liability for negligence (mistakes) or intentional misconduct by signing this consent document.

COSTS

There will be no charge to you or your insurance company for your participation in this study. The study drug, study-related procedures, and study visits will be provided at no charge to you or your insurance company. You or your usual health care payer will be responsible for any other health care costs, not related to the study.

EMERGENCY CONTACT

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study, please contact the study doctor at the telephone number listed on page one of this consent document. If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in a research study being conducted by the study doctor listed on page one of this document.

VOLUNTARY PARTICIPATION / WITHDRAWAL

Your decision to participate in this study is completely voluntary. You may choose to not participate, or you may withdraw from the study for any reason without penalty or loss of benefits to which you are otherwise entitled and without any effect on your future medical care.

The study doctor or the sponsor can stop your participation at any time without your

consent for the following reasons:

- If it appears to be medically harmful to you
- If you fail to follow directions for participating in the study
- If it is discovered that you do not meet the study requirements
- If the study is cancelled
- For administrative reasons, the target number of subjects has entered the study treatment phase;

If you discontinue study treatment prior to Visit Week 48 you will be asked to remain in the study to complete all remaining study visits during the study treatment period. If you agree to continue to be followed post study treatment discontinuation you may be asked to sign an ICF addendum at that time. You will complete a Study Treatment Discontinuation / Withdrawal Visit prior to transitioning back to your regularly scheduled study visits. Study treatment discontinuation subjects will discuss with the study doctor or their provider the appropriate HIV medications for treatment.

If you choose not to continue with study assessments, you will complete the Study Treatment Discontinuation/Withdrawal Visit and be returned to the appropriate HIV medication that the study doctor or your provider deems appropriate.

If you decide to stop taking the study drug, please contact the study doctor. If you leave the study for any reason, the study doctor may ask you to have some end-of-study tests for your safety. Stopping the study drug without a new HIV drug planned transition to follow-up care for HIV could cause your HIV disease to worsen. It is not possible to remove your data that has been already collected from this study in case you withdraw. The data already collected may need to continue to be used to preserve scientific validity in compliance with health regulatory requirements.

GETTING ANSWERS TO YOUR QUESTIONS OR CONCERNS ABOUT THE STUDY

You can ask questions about this consent form or the study (before you decide to start the study, at any time during the study, or after completion of the study). Questions may include:

- Who to contact in the case of a research-related injury or illness;
- Payment or compensation for being in the study, if any;
- Your responsibilities as a study subject;
- Eligibility to participate in the research;
- The study doctor's or study site's decision to exclude you from participation;
- Results of tests and/or procedures;
- Other questions, concerns, or complaints.

Contact the study doctor or study staff <u>listed on the first page of this form</u> with any questions, concerns or complaints.

GETTING ANSWERS TO YOUR QUESTIONS ABOUT YOUR RIGHTS AS A RESEARCH SUBJECT

This study has been reviewed by an Institutional Review Board (IRB). This Committee reviewed this study to help ensure that your rights and welfare are protected and that this study is carried out in an ethical manner.

For questions about your rights as a research subject, contact:

- By mail:
  Study Subject Adviser
  Chesapeake IRB
  6940 Columbia Gateway Drive, Suite 110
  Columbia, MD 21046
- or call **toll free**: 877-992-4724
- or by **email**: adviser@chesapeakeirb.com

Please reference the following number when contacting the Study Subject Adviser: Pro00024555.

PRIMARY CARE PHYSICIAN / SPECIALIST NOTIFICATION OPTION

Please indicate below whether you want us to notify your primary care physician or your specialist of your participation in this study.

_____Yes, I want the study doctor to inform my primary care physician/specialist of my participation in this study.

_____No, I do not want the study doctor to inform my primary care physician/specialist of my participation in this study.

_____I do not have a primary care physician/specialist.

_____The study doctor is my primary care physician/specialist.

Authorization to Use and Disclose Records

During this study your Study Doctor, study nurses and other study site personnel will record information about you, your health and your participation in the study on forms provided by Sponsor. These forms are known as case report forms. You will not be able to participate in this study if you do not consent to the collection of this information about you.

The information collected about you, will be held by the study site, Sponsor and Sponsor's authorized representatives. To ensure that your personal information is kept confidential, your name and any other information that allows you to be identified directly will not be entered on the case report forms or included in any records or samples your study doctor provides to Sponsor or Sponsor's authorized representatives. Instead, you will only be identified by a code. The code is used so that your doctor can identify you if necessary.

The Sponsor and its authorized representatives will analyze and use the coded information they receive for the purposes of this study. Such purposes include:

- checking your suitability to take part in the study,
- monitoring your study treatment with the study drug,
- comparing and pooling your study treatment results with those of other subjects in clinical studies,
- establishing whether the study drug meets the appropriate standards of safety set by the authorities,
- establishing whether the study drug is effective,
- supporting the development of the study drug,
- supporting the licensing application for regulatory approval of the study drug anywhere in the world,
- supporting the marketing, distribution, sale and use of the study drug anywhere in the world, and/or
- as otherwise required or authorized by law.

Your coded study information may also be used for additional unanticipated medical and/or scientific research projects in the future relating to your disease or similar diseases and development of the study drug (but at all times in compliance with applicable law and regulation).

If necessary for these purposes, the Sponsor may share your information with its affiliates, people and companies with whom the Sponsor works, Chesapeake IRB and regulatory or other governmental agencies, such as the FDA. Although efforts will be made to protect your privacy, absolute confidentiality of your records cannot be guaranteed. Your medical information and records may be re-disclosed and no longer protected by federal privacy law.

As explained in this consent form, your participation in this study is voluntary and you

may withdraw from the study at any time by informing your Study Doctor. By signing this consent, you authorize the collection and use of information about you as described in this consent. You may revoke (take back) this authorization for the collection and use of information about you by informing your Study Doctor in writing at the address listed on the first page of this form. If you withdraw from the study or if you revoke your authorization for the collection and use of information about you, your participation in the study will end and the study personnel will stop collecting information from you. The Sponsor will need to keep and use any research results that have already been collected. The Sponsor must do this to comply with its legal obligations and to maintain the scientific integrity of the study. Your decision to withdraw from the study or to revoke your authorization for the collection and use of information about you will not result in any penalty or loss of access to treatment or other benefits to which you are entitled. This authorization has no expiration date, unless and until you revoke it.

In California and any other state that requires an expiration date, the authorization will expire 50 years after you sign and date this authorization document.

Your right to access your health data in the study records will be suspended during the study to keep from changing the study results. When the study is over, you can access your study health data.

If you decide not to sign this form, you will not be able to take part in the study.

You will be given a signed and dated copy of this form to keep.

If you have any questions about the collection and use of information about you, you should ask your Study Doctor.

WHERE CAN YOU FIND MORE INFORMATION ABOUT THIS STUDY?

A description of this clinical trial will be available on http://www.ClinicalTrials.gov as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

AGREEMENT TO BE IN THE STUDY

By signing this informed consent form, I acknowledge that:

(1) I have carefully read and understand the information in this form.
(2) The purpose and procedures of this research study have been fully explained to me. I was able to ask questions and all of my questions were answered to my satisfaction.
(3) I have been informed of the study drugs and procedures of the study that are being tested. I have been informed of possible risks as a result of taking part in this study that could happen from both known and unknown causes.
(4) I understand that I am free to withdraw my consent and to stop my participation in this study at any time. The possible effect on my health, if any, of stopping the study early has been explained to me.
(5) I understand that stopping the study will not impact my medical care and treatment options.

Subject:

Subject Printed Name	Signature	Date

Person Obtaining Consent:

Printed Name & Title	Signature	Date

Witness (if applicable):

Witness Printed Name	Signature	Date

The study subject has indicated that he/she is unable to read. The ICF document has been read to the subject by a member of the study staff, discussed with the subject by a member of the study staff, and the subject has been given an opportunity to ask questions of the study staff.

_____
Printed Name of Impartial Witness

_____ _____
Signature of Impartial Witness* Date

*Impartial Witness: A person, who is independent of the trial, who cannot be unfairly influenced by people involved with the trial, who attends the informed consent process if the subject cannot read, and who reads the informed consent and any other written information supplied to the subject. **Guidance for Industry E6 Good Clinical Practice: Consolidated Guidance**

AGREEMENT FOR USE AND DISCLOSURE OF PROTECTED HEALTH INFORMATION

I hereby authorize the use and disclosure of my protected health information for this study.

Subject:

Subject Printed Name	Signature	Date

Person Obtaining Consent:

Printed Name & Title	Signature	Date

Witness (if applicable):

Witness Printed Name	Signature	Date

The study subject has indicated that he/she is unable to read. The authorization has been read to the subject by a member of the study staff, discussed with the subject by a member of the study staff, and the subject has been given an opportunity to ask questions of the study staff.

_____
Printed Name of Impartial Witness

_____ _____
Signature of Impartial Witness* Date

*Impartial Witness: A person, who is independent of the trial, who cannot be unfairly influenced by people involved with the trial, who attends the informed consent process if the subject cannot read, and who reads the informed consent and any other written information supplied to the subject. **Guidance for Industry E6 Good Clinical Practice: Consolidated Guidance**